Budget Neutrality and Data Systems

(Please see attached document on Budget Neutrality relevant data points)

RESPONSE:

Georgia was only provided with the referenced document regarding data points in the budget-neutrality analysis and will respond separately.

1) The footnote on page 48 indicates that the State has conducted an analysis of its ADAP program to ensure the financial viability if this demonstration is approved. We would like to either see this study or hear more information about it. We are concerned that the growth of the waiver will outstrip funding for ADAP. In addition, we would like to know how this demonstration will affect access to ADAP for individuals that do not qualify for it (i.e. an FPL between 235% -300%).

RESPONSE:

The STD/HIV Section of the Department of Human Resources has developed a spreadsheet to analyze likely future needs of the ADAP population. The spreadsheet, which includes a month-by-month breakdown on prior usage patterns, enables staff to monitor the program's fiscal solvency on an ongoing basis. The State estimates that the program will produce a surplus this year of $795,789, which should be available for roll-over into the following fiscal year.

The State has not yet been informed of the amount of increase in ADAP funding it will receive from the federal government in FY2001 (although Congress approved a healthy increase in December 2000). Likewise, the Title I planning council has not provided definitive information regarding the amount of funding it will allot to ADAP, although the State has requested, and expects to receive, a significant increase in the Title I program's base award. In addition, the State legislature is expected later this session to give approval to the Governor's request for a $4.3 million increase in State tax-levy support for the ADAP program in the upcoming fiscal year.

On the basis of increases in utilization in recent years, the State anticipates that more than 5,600 people will be enrolled in the program by June 2002. Although uncertainties remain regarding available funding in 2001-2002 (as explained in the prior paragraph), the State has a high degree of confidence – based on the above-noted likelihood of substantial additional funding from multiple sources – that funding will be more than sufficient to address anticipated need.

Both the existing ADAP program and the proposed demonstration project serve the same population – namely, low-income, non-disabled persons with HIV who have no means of covering the costs of HIV care, including drugs. Although Georgia acknowledges that ADAP is a critical component of the proposed demonstration project, it submits that the future strains on ADAP will occur regardless of the waiver, given the increases in caseload that all state ADAP programs are experiencing.

Fortunately, the ADAP program enjoys strong bipartisan support – in the U.S. Congress and among Georgia legislators. Federal funding for ADAP increased 11-fold from FY1996 to FY2001 – from $52 million to more than $571 million. Between FY1998 and FY2001, ADAP funding

more than doubled. Likewise, the State has significantly increased its own financial commitment to the program.

In light of the program's strong support from both political parties, among consumers and health care providers, and from the pharmaceutical industry, the State anticipates that funding for the program will continue to grow, as it has annually since the program's inception. The Departments of Community Health (DCH) and Human Resources (DHR) will continue their regular monitoring of the financial solvency of Georgia's ADAP program and will swiftly alert the Governor if indications arise of a potential shortfall.

With respect to persons whose income falls between 235 – 300% of the federal poverty level, ADAP will continue to provide these individuals with the complete ADAP formulary, including all approved antiretroviral drugs and medications to treat and/or prevent opportunistic infections.

2) Please provide a walk-through of the assumptions/formulas used to derive the costs to Medicaid with and without the waiver.

RESPONSE:

As explained in the State's application (dated October 30, 2000), PricewaterhouseCoopers developed the underlying economic model on the basis of data from the Maryland Medicaid program and from the HIV Costs and Services Utilization Survey. As further explained in the application, various data inputs were changed to reflect actual HIV care experience in Georgia, although Maryland/HCSUS inputs were retained where insufficient data existed specific to Georgia. In addition, certain assumptions were built into the model to reflect the anticipated impact of the proposed demonstration project and access to, and quality of, HIV care.

The following alterations were made to the model in the no-waiver scenario:

- As originally designed, the model provided for a single assessment of cost-neutrality for a static population. Rather than enroll 6,500 individuals on Day One of the demonstration project, however, Georgia proposes to enroll the target population in three phases over three to five years. Accordingly, the model was altered to reflect the phase-in proposed by Georgia.

- In the absence of the waiver, Georgia assumes that 60% of individuals eligible for the demonstration project are not currently receiving highly active antiretroviral therapy (HAART), that 30% are currently on a HAART regimen that was initiated rather late in the course of their HIV infection, and that 10% are currently on a HAART regimen that was initiated in a timely manner, in accordance with federal treatment guidelines. Georgia bases its assumptions on three pieces of evidence: First, excluding Medicare-eligible ADAP recipients, the State estimates that the number of ADAP recipients currently receiving HAART is roughly equivalent to approximately 40% of those eligible to participate in the waiver. Given the centrality of ADAP in existing safety-net programs, Georgia assumes that waiver-eligible individuals who are not enrolled in ADAP (or 60% of the eligible population) are not currently receiving HAART. Second, the rather large percentages assigned to the no-HAART and late-HAART categories are supported by national data indicating that the typical person with HIV is diagnosed rather late in the course of disease – often in the hospital and usually in response

to HIV-related symptoms. (Hecht et al., 1998; Wortley et al., 1995.) Third, HCSUS researchers found that one-half of all persons with diagnosed HIV infection are not in regular care, with somewhat higher percentages in the South. (Bozzette et al., 1998.) Due to the rigorous monitoring requirements associated with HAART, the State assumes that persons who are not in care are not receiving HAART.

- Georgia assumes that 30% of the eligible population has CD4 counts higher than 500, that 45% have between 350-500CD4, that 15% have between 200-350, that 5% have between 50-200, and that 5% have fewer than 50 CD4. To derive these assumptions, Georgia began with the most representative sample in the State of HIV-infected persons in care – the Adult Spectrum of Disease (ASD) survey site at AIDS Research Consortium of Atlanta. In the Georgia ASD site, approximately 20% of patients have CD4 counts higher than 500, more than 42% have CD4 counts between 200 and 500, more than 20% have CD4 counts between 50 and 200, nearly 14% have CD4 counts under 50, and insufficient data are available regarding the small remainder of patients. Adjustments to this representative data set were necessary, however, in light of the State's assumption that the demonstration project population will include a disproportionately small percentage of persons with late-stage disease, as such persons are generally already eligible for regular Medicaid benefits. Accordingly, to reach the final estimates of CD4 distribution, the State substantially reduced the estimated share of patients with late-stage disease, which required a corresponding upper adjustment to the percentages of patients with less severe disease.

- The State assumes that 100% of the eligible population would, in the absence of the waiver, be enrolled in Medicaid by Year 7. This assumption is derived from the following: substantial natural history data indicating that persons with untreated HIV infection are normally diagnosed with full-blown AIDS between 8-10 years after initial infection, the fact that most people with HIV are first diagnosed long after initial exposure to the virus, and the fact that the eligible population is comprised of low-income persons who lack health coverage (i.e., the population that has traditionally looked to Medicaid for health coverage upon becoming disabled). Based on the assumption that 100% of the eligible population would be enrolled in Medicaid by Year 7 without the waiver, the economic model assumes an annual 18% transition of the population into Medicaid.

- Due to the disabling nature of HIV disease, it is assumed that no person who became eligible for Medicaid in the absence of the waiver would leave the program after enrolling.

- No changes were made to the model's underlying inputs regarding the cost of HIV drugs, as Georgia is unaware of substantial variations in such costs between regions. Because geographic variations are common with regard to the costs of hospitalization and physician services, the State compared the model's inputs for non-drug Medicaid costs in the absence of the waiver (which were derived from Maryland's experience several years ago) with actual HIV-related cost data from Georgia's own Medicaid program. The comparison revealed that the model's standard inputs dramatically understated actual HIV-related non-drug costs to Georgia's Medicaid program. Average length of hospital stay for a Georgia Medicaid recipient is 30 days – substantially higher than national norms. Average annual hospital cost per HIV-positive Medicaid recipient in Georgia is $18,733.90 – a figure that substantially exceeds (by more than 20%) annual non-HAART costs ($15,576) of the very sickest HIV-positive Medicaid recipients

in Maryland (i.e., those with fewer than 50 CD4). On the basis of such evidence, Georgia adopted a *conservative* upward adjustment of 20% for non-HAART costs in the no-waiver scenario.

The following alterations were made to model in the waiver scenario:

- Georgia assumes that 85% of enrollees under the waiver will receive HAART in a timely manner, while 15% will receive late HAART. Georgia assumes that all patients for whom HAART is medically indicated will obtain such therapy. This assumption is based on Georgia's proposed rigorous quality assurance measures, mandated intensive case management, and close coordination between ADAP and the demonstration project. Despite the demonstration project's alignment of provider incentives to encourage more aggressive outreach and case-finding, the State assumes that some patients (the assumed 15% in the "late HAART" category) will nevertheless fail to initiate therapy at an appropriately early stage of infection.

- Georgia assumes a 20% reduction in non-drug costs (over and above the Maryland experience) as a result of the waiver. Georgia anticipates that the demonstration project will significantly improve adherence rates and reduce the frequency with which inappropriate regimens are prescribed, which in turn will enhance medical outcomes and thereby reduce hospitalization rates. These outcomes, which lead to the assumed downward adjustment in costs, will flow from the demonstration project's proposed implementation of a rigorous clinic-based case management system, initiation of comprehensive quality assurance measures, and coverage of mental health and substance abuse services.

3) Page 17, "Eighty-five percent of ADAP recipients in Georgia are currently on HAART." Please explain the 85%. According to the HRSA ADAP Branch estimates, currently approximately 100% of the ADAP recipients are on HAART. It may be, for example, if individuals are not receiving all of the HAART drug therapies from ADAP they may be receiving them from various other sources, for example, the VA or other systems of health care.

RESPONSE:

In contrast to the HRSA estimate, the 85% figure is based on Georgia's actual experience with its ADAP population. The State submits that this figure accords with what one might reasonably anticipate. HAART is not medically indicated for all people with HIV infection, particularly in the absence of laboratory evidence of viral activity. In addition, State officials indicate that ADAP data suggest that some physicians may be prescribing inappropriate (i.e., non-HAART) antiretroviral regimens.

It is highly unlikely that a meaningful number of ADAP recipients are receiving a portion of their drugs from another source, such as the Veterans Administration. Georgia's ADAP program rigorously collects information regarding recipients' potential health care options (in part, to satisfy federal mandates that Ryan White serve as the payer of last resort). Only 8% of ADAP recipients in Georgia have any form of federally-financed health care other than Ryan White, and it is believed that virtually all such individuals depend on Medicare (which, of course, does not include outpatient drugs). For the 90% of ADAP recipients who are uninsured, they must look to safety-

net providers, all of whom (as noted in the application) depend wholly on the ADAP program to provide their patients with antiretrovirals.

Indeed, the notion that substantial percentages of Georgia's ADAP population are receiving antiretroviral drugs elsewhere is somewhat counter-intuitive. There is no well-developed health care safety net in Georgia. While safety-net providers might occasionally be able to provide their HIV-positive patients with Bactrim or other relatively inexpensive OI medications, it is extraordinarily unlikely that such providers would have the financial capacity to underwrite the cost of even a single antiretroviral agent.

4) Page 6, is the decrease in AIDS cases in Georgia of 66% (from 2233 in 1994 to 768 in 1999) due to HAART consistent with the earlier statement that many individuals are receiving sub-optimal HAART? Since the State does not currently have HIV reporting, can Georgia track an accurate number of new HIV infections by risk category and demographics? Does the State have plans to move to an HIV reporting system so that they can obtain a more objective measure of those individuals likely served by this waiver? If not, how does the State plan to review new HIV infections?

RESPONSE:

Georgia's decline in cases largely tracks national experience. As in Georgia, this national decline in cases has occurred at the same time that evidence has emerged of serious shortcomings in our HIV care infrastructure. Cases have declined nationally, for example, even though the landmark HCSUS has documented that one in two persons with diagnosed infection are not in regular care. The downward trend in AIDS cases – which, parenthetically, has begun to plateau – primarily reflects the therapeutic power of HAART. Georgia's proposed demonstration project is premised on the belief that even greater declines are possible, if quality HIV care is extended to those who currently lack it.

Georgia currently has no system for reporting HIV infection. The State, however, is assessing options for implementing a comprehensive system of HIV reporting – either through a name-based reporting system or one that relies on unique identifiers.

<u>Eligibility, Outreach, and Enrollment</u>

5) On page 6, the State mentioned that the percentage of AIDS cases among homosexuals and IV drug users had declined and the number of HIV cases among heterosexuals, especially African-Americans and women, were increasing. How does the State account for this? What outreach efforts is the State undertaking to educate and to promote prevention and treatment among these communities where the number of cases is increasing? Also, please explain the appropriate media outlets that will be used in the outreach efforts under the demonstration project (page 57).

RESPONSE:

The decline in AIDS cases among homosexuals and injection drug users, as well as the corresponding rise in cases among heterosexuals, African-Americans, and women, reflect broader, national epidemiologic and regional trends. In essence, these trends reflect two well-established

patterns for infectious diseases – the diffusion of the disease beyond the populations who were initially at highest risk, and the tendency over time of sexually transmitted diseases to have a disproportionate effect on persons with lower socioeconomic status.

The State aggressively promotes HIV prevention and treatment within the populations that are increasingly affected by the disease. One need merely look at utilization rates of State HIV programs to recognize the effectiveness of the State's outreach efforts to underserved communities. According to the most recent data available, 72.37% of Title II clients are African-American and almost four in 10 are women.

In Atlanta, the planning council that allocates funding from Title I of the Ryan White CARE Act is a representative body that has prioritized primary care services for underserved populations. At the Infectious Disease Clinic of Grady Memorial Hospital, for example, which receives approximately one-half of metro Atlanta's Title I award, more than 70% of patients are African-American, and 24% are women. In 1999, heterosexual patients at Grady for the first time surpassed gay and bisexual men as the leading patient population.

Likewise, the State has taken aggressive steps to support HIV prevention outreach to communities of color. Like all other jurisdictions that receive HIV prevention funds from the Centers for Disease Control and Prevention, the State of Georgia uses a community planning model to prioritize prevention spending. The most recent prioritization process, which was based on a comprehensive needs assessment and which governs current spending, identifies subpopulations of African-Americans as the three top priorities – African-American heterosexual men and women between 13-19, African-American men who have sex with men between 13-19, and male and female African-American injection drug users ages 20-29. On the basis of these priorities, the State has directed funding to numerous organizations with roots in the communities identified as prevention priorities.

In addition to funding for general prevention and care services targeted to African-Americans, the State has initiated two special initiatives targeting communities of color. First, in an effort to prevent mother-to-child transmission of the virus, the HIV prevention perinatal project promotes awareness of HIV status and prenatal care among pregnant women. This project underwrites a social marketing campaign using television, radio, and print media; provides for intensive case management for women at high risk of infection; and sponsors professional education for the medical community. Second, the State supports transitional planning for persons leaving correctional facilities, ensuring that HIV-positive inmates receive the care they need when they return to their communities.

With respect to media outlets to be used to promote and publicize the demonstration project, the State anticipates using radio, local newspapers, small media in association with community outreach, and press releases to generate free media coverage. In all such cases, efforts will be made to ensure that such media outreach is appropriately targeted to populations with high HIV prevalence and incidence.

Finally, the State has the distinct advantage of having the agencies responsible for Minority Health, Women's Health, and Rural Health under the same administrative agency as the Medicaid program, the Department of Community Health. Outreach efforts will be coordinated and comprehensive.

6) Besides ADAP, the Medicaid data system, and the Grady Memorial Hospital Infectious Disease Center (IDC), what other avenues is the State looking at to ensure that all possible HIV risk groups are being reached? (page 16)

RESPONSE:

As set forth in the application's discussion of available payer sources and HIV care infrastructure, the State has, in developing its proposed demonstration project, exhaustively studied and analyzed experience under Title I of the Ryan White CARE Act, Title II of the Ryan White CARE Act (including the ADAP program), Title III of the Ryan White CARE Act, Medicaid, the Infectious Disease Clinic of Grady Memorial Hospital, and the Adult Spectrum of Disease site at AIDS Research Consortium of Atlanta. The Offices of Women's Health and the Office of Minority Health will also participate.

With respect to the HIV Centers of Excellence proposed in the demonstration project, the State proposes to issue an RFP for health care providers interested in being designated as an HIV center. Although this competitive process will be open to all safety-net providers, the State anticipates (on the basis of available information regarding HIV care expertise in Georgia) that this statewide network will likely be comprised of, at least, Grady Memorial Hospital, one or more early intervention clinics in the Atlanta metropolitan area currently funded through Title I of the Ryan White CARE Act, the Ryan White Title III clinics, and the primary care clinics presently funded through Title II. The State submits that this statewide network will collectively have an impressive record of serving low-income persons with HIV in Georgia and reaching those most at risk. In contrast to current practice, the demonstration project will for the first time offer these providers powerful financial incentives to strengthen their ties to communities at greatest risk and to undertake aggressive outreach and case-finding activities to encourage people to access care at an earlier stage of disease.

7) Page 47, the State indicates that Medicare beneficiaries will not be covered under the waiver. We understand that this may be a way for the State to increase the likelihood of cost effectiveness; however, since approximately 22% of Grady Hospital's HIV patients are Medicare eligible, this will leave a significant portion of the population without the benefits of the Centers of Excellence and the intensive case management which promotes treatment adherence. Since the Medicare beneficiaries should not be too expensive relative to the other services covered under the waiver (because Medicare will cover most of them) and ADAP would be paying for HAART, would the State ever consider covering Medicare beneficiaries?

RESPONSE:

The proposed demonstration project is intended to address the urgent medical needs of persons who have no effective means to obtain appropriate primary care related to their HIV infection. With access to HIV drugs afforded by ADAP, low-income Medicare beneficiaries currently have the means to obtain a meaningful continuum of HIV-related medical services. As such, they are not the primary focus for the State's proposal to expand HIV care.

The State observes, however, that the safety-net providers surveyed in connection with development of the proposed demonstration project have extensive experience in treating HIV-positive Medicare beneficiaries. Grady's Infectious Disease Clinic, as noted, has substantial

numbers of Medicare recipients among its patients, and the Title III clinics in Georgia similarly treat Medicare patients. As noted earlier, the State anticipates that these well-established HIV safety-net providers may be likely to become HIV Centers of Excellence under the demonstration project. Although the demonstration project proposed here focuses on low-income persons with no effective means to obtain comprehensive primary care, it is the State's hope and expectation that the HIV Centers of Excellence established through the demonstration project will quickly become the central HIV care network for the entire State, attracting Medicaid, Medicare, and private insurance patients, as well as persons enrolled under the waiver.

8) Is the eligibility criteria for Medicaid under the Section 1931 eligibility group the same as the eligibility criteria for TANF?

RESPONSE:

TANF, of course, is the cash assistance program that replaced Aid to Families with Dependent Children (AFDC). Section 1931 eligibility, also known as the Low Income Medicaid (LIM), replaced AFDC Medicaid. While TANF and LIM have similar eligibility criteria, there are some important differences (e.g., time limits, etc.). In Georgia, almost all TANF eligibles (99%) are eligible for LIM, but not all LIM eligibles are entitled to receive TANF.

9) Page 16: Under ADAP, GA states that "State regulations limit the program to persons with CD4 counts under 500 cells per cubic millimeter..." Will this regulation be changed to allow those individuals in the demonstration with CD4 counts greater than 500 to access ADAP if they and their physician choose to begin HAART?

RESPONSE:

Upon approval of the waiver application, the State intends to open the ADAP program to all income-eligible persons, regardless of CD4 status.

10) P. 57, Outreach: Will the State consider targeting outreach efforts to correctional facilities, including juvenile detention facilities, and possibly half-way houses?

RESPONSE:

Correctional inmates, of course, are not eligible for participation in the demonstration project because their health care services are provided by correctional facilities and systems. Many persons released from correctional settings, however, may be eligible to participate in the demonstration project. Accordingly, the State will, in connection with its other outreach efforts undertaken in connection with the demonstration project, seek to integrate outreach to appropriate correctional facilities (including juvenile detention facilities, and possibly half-way houses) in its efforts to facilitate access of eligible individuals to the services offered through the demonstration project.

11) Can an HIV positive Medicaid eligible enrolled in GBHC choose to receive care at an HIV Center of Excellence?

RESPONSE:

Yes.

Benefits

12) Please describe how beneficiaries will access the Centers of Excellence.

RESPONSE:

Extensive outreach by the State will raise public awareness of the demonstration project throughout the state. As part of such outreach, the State will educate HIV service networks, including community-based case managers and staff at voluntary HIV counseling and testing sites, of the availability of services under the demonstration project.

Such efforts will facilitate routine referral of potentially eligible individuals to the demonstration project. At entry, eligible individuals will be thoroughly informed of all aspects of the demonstration project, will be asked to give their consent to participate, and may choose the HIV Center of Excellence at which they wish to obtain their care. At the Center itself, case management personnel will act as intake counselors, assisting with waiver applications, performing a comprehensive needs assessment, acquainting the enrollee with available services, and assessing the need for additional referrals.

13) Page 51, the State proposes to provide a tailored set of mental health and substance abuse services through an existing Community Service Board (CSB) program. Will this be the same set of services currently provided in Medicaid or expanded services? If it is to mirror the Medicaid program, what has been the experience of Medicaid with actual access to the services and the success and quality of the services? Is there an adequate provider network?

RESPONSE:

The State proposes to provide the following mental health and substance abuse services through the demonstration project: nurse assessment and education; physician assessment and care; individual therapy; family therapy; group therapy; intensive outpatient substance abuse services; and ambulatory detoxification. This service package represents a subset of mental health and substance abuse services currently offered through Medicaid. This limited package has been carefully tailored to respond to the particular needs of the target population and to further the specific aims of the demonstration project, including the maximization of treatment adherence.

To assess the accessibility and quality of current mental health and substance abuse services, the State has created the Georgia Performance Measurement and Evaluation System (PERMES), which uses various methods, including direct observation, to mark progress and indicate areas for adjustment. In connection with PERMES, the State in 1999 used consumer surveyors to elicit information regarding the opinions of recipients of existing mental health and substance abuse services in Georgia. On the basis of more than 9,400 individual consumer surveys, the State determined that nearly 90% of the consumers felt positively about their access to basic services. Approximately 80% also responded positively when asked to evaluate their access to the full range of mental health and substance abuse services, including peer supports and physician access.

The State currently contracts with American Psych System (APS), an external review agency, to ensure the medical appropriateness of mental health and substance abuse services provided through Medicaid, and APS will also monitor such services provided under the demonstration project. As access to these supportive services are critical to ability of the demonstration project to influence treatment adherence for some patients, the State anticipates that its quality assurance and evaluation mechanisms will include specific measures to assess access to, and quality of, the mental health and substance abuse services provided pursuant to the demonstration project.

With respect to provider network, the State Medicaid program already relies on a well-developed network of 29 statutorily created Community Service Boards (CSBs) for the delivery of mental health and substance abuse services to Medicaid recipients. This statewide network of mental health professionals already cares for a Medicaid patient population many times larger than the population targeted by the proposed demonstration project. The proposed demonstration project, as set forth in the application, provides that designated HIV Centers of Excellence must either maintain liaison agreements with the local CSB for the provision of mental health and substance abuse services to enrollees or must demonstrate the capacity and qualifications to provide such services within the Center itself.

14) The waiver indicates that laboratory costs for an HIV-positive Medicaid patients in FY 99 was $392. This would indicate that Georgia is not yet reimbursing for resistance testing. Since studies not only show that the tests preserve the limited repertoire of antiretroviral drugs, but also are cost effective, will the State consider covering these tests in the demonstration and the regular Medicaid program?

RESPONSE:

The Georgia Medicaid program does not currently reimburse for resistance testing, as various aspects of the test (such as cost, frequency, etc.) cannot be accommodated within the existing State laboratory contract. The Division of Community Health has requested that such testing be included in the next contract, which will take effect in 2003.

Through the Ryan White program, however, the State has experience in underwriting the provision of resistance testing to low-income patients with HIV. Both the Title I and Title II programs have informed their medical providers that the program covers genotypic and phenotypic testing.

15) Needs assessments should include an assessment of HIV risk behaviors. HIV prevention counseling services should include prevention case management (PCM) or multi-session intensive counseling for persons who have difficulty initiating or maintaining safer sex and needle-sharing practices. (p. 50) Please address.

RESPONSE:

The State strongly agrees that HIV prevention must be integrated as a fundamental component of the services provided by the HIV Centers of Excellence. The State will ensure that protocols for the Centers emphasize the provision of appropriate prevention services to demonstration project enrollees, including but not limited to an assessment of HIV risk behaviors as part of the initial needs assessment, HIV prevention counseling in connection with ongoing case management, the

use of reimbursable mental health and substance abuse services to promote primary HIV prevention, and referral (where appropriate) of enrollees to CDC-funded HIV prevention services.

Program Structure and Delivery System

16) How does the State plan to assure that there will be a bidder for the Centers of Excellence in each of the 19 districts and that there are experienced providers to provide or oversee care?

RESPONSE:

Extensive consultation with providers currently funded under Titles I, II, and III of the Ryan White CARE Act has demonstrated overwhelming support among HIV safety-net providers for the demonstration project proposed by the State. Such providers currently exist in 17 of the 19 health districts, and the State has a high degree of confidence that at least these existing providers will seek to participate as HIV Centers of Excellence.

Special efforts will be required in the two districts that lack existing Ryan White-funded HIV safety-net providers. In anticipation of the demonstration project's implementation, the State has already begun exploring potential avenues to ensure that each district has an HIV Center of Excellence. One such strategy currently being considered is the development of additional contracts with existing safety-net providers in nearby districts, which would be retained by the State to provide care and services under the demonstration project on specified days to enrollees who reside in the underserved district. The proposed demonstration project provides for the re-direction, if needed, of a portion of the State's base Title II award to support the establishment of new HIV Centers of Excellence in districts that currently lack an HIV safety-net infrastructure.

17) Please explain how providers will be required to account for receipts under the demonstration project separately from the Medicaid reimbursement? (page 55)

RESPONSE:

The State included this provision in response to the concerns expressed by certain HIV safety-net providers that the larger institutions in which their clinics were based might seek to divert the additional funding anticipated from the waiver to cover non-HIV-related care costs. To ensure that demonstration project funds are used exclusively to promote the project's HIV-related objectives, the State will include in its contracts with HIV Centers of Excellence the requirement that centers separately account for funds received through the demonstration project.

Monitoring

18) What is the State proposing regarding provider monitoring?

RESPONSE:

As part of their contracts with the State, HIV Centers of Excellence will be required to adhere to quality of care standards that the State will promulgate. As set forth in the application, peer review and ongoing quality assurance will be built into the demonstration project, and an HIV Quality of Care Committee will monitor performance of the Centers and recommend appropriate action if

and when problems arise. Similarly, the State's external evaluator will also conduct sample chart reviews and report potential problems to the appropriate State officials and to the HIV Quality of Care Committee.

19) How does the State foresee the Centers of Excellence monitoring adherence to drug regimens?

RESPONSE:

Providers' ability to monitor treatment adherence is imperfect because it typically relies to some degree on patients' self-reported behavior. Researchers, however, are actively exploring innovative strategies to monitor and promote patient adherence. (*See* Parienti et al., The Pills Identification Test: A Tool to Assess Adherence to Antiretroviral Therapy, *J.A.M.A.* 2001;285:412; reporting French study regarding use of patient testing to monitor treatment adherence.) In association with the HIV Quality of Care Committee, the State will devise protocols to support providers' efforts to monitor and improve patient adherence to treatment.

In addition, the State submits that other aspects of proposed demonstration project will enhance providers' ability to monitor and improve treatment adherence. The intensive case management protocol, for example, will require frequent, well-documented contacts with patients and identify triggers for heightened case management activities. The State believes that the close and intimate relationship that case managers will forge with demonstration project enrollees will assist the care team at the HIV Center in better monitoring patients' adherence to treatment. Heightened case management should also enhance Centers' ability to identify the need for additional services (such as mental health and substance abuse services) that will improve patients' capacity to adhere to prescribed therapies.

20) The State should consider monitoring and/or measuring at least the following indicators of HIV care:

- **CD4 measurement at six months**
- **Viral load (HIV plasma RNA) testing at six months**
- **Offering ART to patients with CD4 counts less than 350**
- **Offering of PCP prophylaxis to patents with CD4 counts less than 200**

RESPONSE:

The State wholeheartedly agrees with HCFA's suggestion and will integrate these items into the quality of care guidelines that will govern the HIV Centers of Excellence. The State notes that the standard of care in HIV is constantly evolving, necessitating ongoing monitoring by the HIV Quality of Care Committee to revise or add new indicators as additional evidence becomes available.

21) The State should consider using the following HIV prevention indicators in its quality assurance program:

- **The proportion of beneficiaries assessed for HIV risk behaviors**
- **The proportion of beneficiaries receiving HIV risk reduction counseling**

- **The proportion of beneficiaries presenting with a new episode of a sexually transmitted disease**

In addition the State should consider monitoring the degree to which the provision of prevention services, such as prevention counseling and partner notification services, are documented in the chart.

RESPONSE:

The State wholeheartedly agrees with HCFA's suggestion and will integrate these items into its quality of care guidelines and in the ongoing quality assurance monitoring of the HIV Centers of Excellence.

General Comments

22) In collaboration with the George Washington University's Center for Health Services Research and Policy, CDC and HRSA developed "Sample Purchasing Specifications for HIV Infection, AIDS, and HIV-Related Conditions". These prevention and care specifications were developed for use in Medicaid managed care contracts and may be useful in drafting contracts with the HIV Centers of Excellence. They are on GWU's web site at www.gwu.edu/~chsrp.

RESPONSE:

In connection with the drafting of contracts with the HIV Centers of Excellence, the State will review and study the referenced "Sample Purchasing Specifications for HIV Infection, AIDS, and HIV-Related Conditions" to determine their appropriateness and utility in this context.

23) P. 50, paragraph 2, line 4: The diagnosis of a sexually transmitted disease or pregnancy should also be SOURCE program "triggers". The case management should include periodic inquiries about safer sex and needle-sharing practices (if appropriate).

RESPONSE:

The State agrees and will include such diagnoses as triggers for heightened case management activities.

24) P. 52, Centers of Excellence: Providing prevention services within the context of care is preferable to providing referrals for prevention services. Consideration should be given to approaching the health department about the possibility of stationing prevention counselors on-site at Centers of Excellence.

RESPONSE:

The State fully agrees that prevention services targeting persons living with HIV are likely to be more effective if they are integrated into regular care settings. Within budgetary constraints, the State will consider the possibility of stationing prevention counselors on-site at HIV Centers of Excellence. The State believes, however, that the optimal outcome would build genuine

prevention expertise within the patient's care team at the Center. Accordingly, the State also intends to study the viability of training programs to ensure that case managers, nurses, mental health and substance abuse providers, and the primary physicians themselves have the expertise and sensitivity required to counsel enrollees regarding HIV prevention issues.

25) Please provide journal articles which support the following claims:

- **A 20% savings if a Center of Excellence approach is used.**

RESPONSE:

In light of the rudimentary nature of data pertaining to strategies for limiting HIV-related medical costs, the selection of any particular number to project savings under the demonstration project is somewhat arbitrary. The State strongly believes, however, that the 20% figure significantly *understates* the savings that are likely to accrue from the proposed demonstration program. The State's conclusion is based in part on the substantial body of data supporting the demonstration project's underlying theory that comprehensive care management, undertaken at an earlier stage of HIV infection, will delay disease progression and thereby result in savings.

The State's analysis begins with the well-established proposition that cost of care increases substantially as the HIV-positive patient's immune system deteriorates. (*See* Gebo et al., 1999, Appendix S of application; Moore & Chaisson, 1997, Appendix M; Petrou et al., 1996, Appendix M.) In the experience of Maryland's Medicaid program, for example, inpatient costs among patients who took no protease inhibitor were more than twice as high for persons with less than 50 CD4 than for those between 200-500 CD4. (Gebo et al., 1999.) For patients who were on protease inhibitors, inpatient costs for persons under 50 CD4 were nearly 25 times higher than for their counterparts who had between 200-500 CD4. (*Id.*)

The State seeks to improve health outcomes *and* reduce HIV-associated medical costs by intervening early to prevent progression to more serious, and costly, disease. The State hopes to achieve this by three means.

First, the demonstration project will promote access to HAART –

- by removing financial barriers to care;
- by developing a statewide network of HIV Centers of Excellence, ensuring that all persons with HIV in Georgia have meaningful access to care, especially in presently underserved parts of the State;
- by creating incentives for health care providers to undertake aggressive testing campaigns and case-finding outreach to bring people into care in a more timely manner;
- by supporting aggressive management of HIV-infected patients, ensuring that HAART is initiated as soon as it is medically indicated; and

- by generating increased public awareness of the availability of life-saving medications through the demonstration project, thereby encouraging persons with HIV to voluntarily seek care.

HAART slows disease progression, delaying or preventing the emergence of serious opportunistic illnesses that often require expensive hospitalization. (*See* Miller et al., 1999, Appendix L; Mouton et al., 1997, Appendix N; Gebo et al., 1998, Appendix N; Eng et al., 1999, Appendix N; Stansell et al., 1999, Appendix N; Keiser et al., 1999, Appendix N; Torres & Barr, 1997, Appendix N.) In one illustrative study, for example, initiation of protease inhibitors resulted in a 41% decline in HIV-related health care costs over 2.5 years, primarily as a result of a decrease in HIV-related hospital days. (Keiser et al., 1999, Appendix N.) By increasing access to HAART, the demonstration project will improve health outcomes, slow HIV-related disease progression, and reap associated savings in HIV-related medical costs.

Second, the demonstration project will maximize treatment adherence. The demonstration project will achieve this objective –

- through intensive case management;

- by organizing care at the HIV centers of excellence in consumer-friendly, physician-supervised care management teams;

- by providing centers with financial incentives to ensure consistency and availability of care; and

- by covering critical ancillary services, including mental health and substance abuse services.

Promoting adherence will have a significant impact on HIV-related medical outcomes and, by extension, on HIV-related medical costs. Substantial evidence indicates that careful adherence is necessary to ensure the success of HAART. (*See* Paterson et al., 2000, Appendix O.) HAART failure, of course, is associated with re-emergence of viral activity and deterioration of the immune system, which in turn leads to greater average HIV-related medical costs. By maximizing treatment adherence, the demonstration project helps maximize the cost-effectiveness of HIV care.

Third, the demonstration project will ensure the highest quality of HIV care. As the application makes plain, an important subset of HIV-infected patients in Georgia obtain improper medical management of their disease, most notably in the form of substandard antiretroviral regimens. This accords with national experience. The national HCSUS study, for example, documented the widespread prescription of inappropriate treatment regimens to HIV-infected patients. (Shapiro et al., 1999, Appendix F.) Studies have consistently correlated providers' HIV-related clinical experience with enhanced health care outcomes for HIV-positive patients. (*See* studies in Appendix Q.)

The demonstration project will promote high-quality care –

- by requiring that enrollees receive their care at designated HIV Centers of Excellence;

- by implementing aggressive, rigorously enforced quality-of-care guidelines through the HIV Quality of Care Committee;

- by evaluating quality of care through the State's evaluation contractor's sample chart review; and

- by ensuring appropriate training of staff in HIV Centers of Excellence.

Improper care increases the likelihood that HIV disease will progress faster, leading to higher hospitalization costs. The numerous studies appended to the application (Appendix L) indicate that non-HAART antiretroviral regimens produce substantially inferior health care outcomes than HAART regimens. By maximizing the likelihood that prescribed therapy under the demonstration project will accord with federal treatment guidelines, the State enhances the effectiveness – and cost-effectiveness – of HIV care.

In summary, the evidence is overwhelming that the approach adopted by the State is exceptionally well-calculated to produce excellent, cost-effective medical outcomes for Georgia's population of low-income, uninsured, HIV-positive population.

- **The transitional probability distributions used for early and late HAART with particular stress on those in a later HIV stage reverting back to a less severe stage.**

  The transitional probabilities are based on unpublished information supplied to PricewaterhouseCoopers by HCSUS researchers.

26) The assumption that every patient "who qualifies for HAART will receive it" is optimal; however, many people are unable to bear the side effects and choose not to begin drug therapy until in late stage disease. Many active substance abusers are not good candidates for HAART, and a few are on salvage therapies that may not be recommended HAART therapies. The latest publication from follow-up 2 in the HCSUS states that only 53 percent of the people not lost to follow-up or death were receiving HAART. Please address the State's approach.

RESPONSE:

The demonstration project is designed to ensure that every patient, regardless of treatment history, benefits from optimal medical management. The demonstration project's expansive coverage of laboratory testing and physician office visits enhances the likelihood that treatment decisions will be based on sound medical evidence of what is best for the patient. For the typical patient in the eligible population without a long history of antiretroviral treatment, this will mean that a recommended antiretroviral combination will be initiated as soon as it is medically indicated. For the relatively small number of heavily pre-treated patients in the eligible population, this will mean the clinician's careful consideration of available options for salvage therapy. In short, the goal of the demonstration project is to ensure the best possible care for Georgia's HIV-infected population, regardless of stage of disease or treatment history.

The State recognizes that barriers such as substance addiction and chronic mental illness impede some patients' ability to adhere to complex treatment regimens. This is a key reason why the State

included expansive coverage of mental health and substance abuse services in the demonstration project's benefit package. While it is probably inevitable that some patients may never be able to adhere to HAART, the State aims to achieve as close as possible 100% coverage of HAART for those persons for whom the regimen is medically indicated.

Operational Protocol

27) P. 50, paragraph 2, line 7: Prevention case management should be included in the protocol for the HIV case management benefit. Georgia's HIV/AIDS Needs Assessment documented the need to expand prevention case management.

RESPONSE:

The State agrees and will include prevention case management as part of the HIV case management benefit.

28) Page 73, how will the demonstration ensure that mental health and substance abuse services are readily available to those who need them? What specific methods will the providers use to increase adherence, and what documentation will be required of providers to show effectiveness?

RESPONSE:

As part of the RFP, prospective Centers of Excellence will be required to articulate a meaningful plan to ensure ready access to mental health and substance abuse services to patients for whom such services are indicated. Such requirements will become provisions of the contracts between the State and the Centers of Excellence. Likewise, documentation sufficient to demonstrate reacy access to, and utilization of, quality mental health and substance abuse services will be mandated by the State's new case management benefit, and relevant criteria will be identified in the case management protocol as "triggers" for heightened case management attention. With input from the Quality of Care Committee, the Community Advisory Board, relevant State officials, and other experts, the State will ensure that quality assurance criteria include sufficient monitoring of patients' ready access to mental health and substance abuse services. In addition, the State will work with its evaluation contractor to develop meaningful measures to gauge Centers' success to facilitating access to high-quality mental health and substance abuse services.